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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,532	02/22/2002	Malcolm L. Gefter	PPI-107	8658

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,532	GEFTER, MALCOLM L.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) *1-45 and 57-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/18/04, 11/25/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group XV (claims 46-56) in the reply filed on 7/9/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-63 are pending in the instant application. Claims 1-45 and 57-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Information Disclosure Statement

Receipt is acknowledged of a pair of information disclosure statements (IDSs) filed on 6/18/2004 and 11/25/2002. The signed and initialed PTO Form 1449 for each IDS has been mailed along with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46 to 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is vague and indefinite in that the metes and bounds of the phrase "determining the nucleic acid sequence of step (a) in the cell of step (c)" are unclear. There is no clear and

positive prior antecedent basis for the nucleic acid sequence of part (a). Nor is there a clear and positive prior antecedent basis for the cell in part (c) of the claim. This makes it unclear how one actually identifies a peptide that modulates the infectivity of the pathogenic organism.

Claims 47-49 recite the limitation of cells "derived from" a particular source. It is unclear the nature and number of steps required in order to obtain a "derivative" of another cell type. It would be remedial to amend the claim language to recite, "obtained from", which implies a much more direct method of providing the recited cells.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (U.S. Patent No. 6,737,241; see the entire patent) in view of Gaynor et al (U.S. Patent No. 5,597,895; see the entire patent) and Mehtali et al (U.S. Patent No. 5,981,258; see the entire patent).

Nolan (the '241 patent) teaches methods for screening for transdominant intracellular effector peptides and RNA molecules inside living cells (e.g. abstract). In the methods taught by Nolan, randomized or biased-randomized peptides are expressed from a library of expression constructs in a plurality of host cells (e.g. column 17, lines 44-67). The peptides expressed can be 4 amino acid residues up to about 100 amino acid residues in length (column 3) and can be based on known domains present in a given polypeptide (i.e. polypeptide fragments of a known

protein (e.g. columns 15-16). The host cell can be any mammalian cell, including primate or human cells (e.g. column 20, lines 21-35). The '241 patent specifically contemplate assaying the peptide library in the plurality of transformed cells for the ability to modulate infection by viral and cellular pathogens and determining the nucleic acid sequence of library members in order to identify the sequence of the selected peptides (i.e. parts (c) to (e) of the rejected claims; e.g. HIV-1, HSV, mycobacteria, T. cruzi, salmonella, etc.; e.g. column 22, column 31, claims 1-10).

The '241 patent teaches each of the limitations recited in the rejected claims except that it does not explicitly teach that the peptide library comprises fragments of one or more proteins that are encoded by the genome of the pathogenic organism itself.

Gaynor et al teach the characterization and use of various HIV Tat protein mutants, including truncated mutants of 72 amino acids or less that are trans-dominant with regard to Tat function and which inhibit virus replication (e.g. the abstract). Gaynor is not anticipatory of the instant claims because it does not explicitly teach contacting cells comprising the expression constructs of their invention with the virus in order to identify clones that inhibit infectivity by the virus.

Mehtali et al teach that pathogenic organisms can comprise multiple proteins that are targets for trans-dominant effects that inhibit infectivity by the pathogenic organism. Specifically, Mehtali et al teach compositions comprising a combination of trans-dominant variants of two viral proteins from a single virus (i.e. HIV Rev and Tat). While Mehtali et al teach that the mutant Tat and Rev proteins can be generated by deletion of the wildtype sequence, the patent does not reduce to practice such an embodiment (columns 2, lines 28-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Nolan to include the use of peptides obtained from the protein complement of a particular pathogen in order to identify trans-dominant peptides that modulate infection by the pathogen because (i) Nolan teaches it is within the skill of the art to utilize random or biased peptide libraries to identify transdominant peptides capable of inhibiting infection for a number of different pathogens and (ii) Gaynor et al and Mehtali et al teach that such transdominant peptides can be obtained from proteins expressed by the pathogen itself. One would have been motivated to do so in order to receive the expected benefit of using the pathogen's protein complement to obtain trans-dominant peptides that interfere with infectivity by the pathogen. Absent evidence to the contrary, there would have been a reasonable expectation of success in modifying the teachings of Nolan to include the use of peptides derived from the protein complement of the pathogen itself in order to obtain trans-dominant peptides that modulate the infectivity of pathogen.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

ggl

GERRY LEFFERS
PRIMARY EXAMINER